

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Maertens et al

Atty. Ref.: **2752-50**

Divisional of Serial No. **09/378,900**

Group:

Filed: **July 6, 2001**

Examiner:

For: **PROCESS FOR TYPING OF HCV ISOLATES**

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July 6, 2001

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Preliminary amend the above-identified application as follows.

IN THE SPECIFICATION

Amend the specification as follows.

Insert the attached Sequence Listing after the claims pages.

IN THE CLAIMS

Amend the claims as follows.

Cancel claims 1-23, without prejudice.

Insert the following claims:

--24. (new) A polynucleic acid selected from the group consisting of

CCC TGT GAG GAA CTW CTG TCT TCA CGC (SEQ ID NO 1),

GGT GCA CGG TCT ACG AGA CCT (SEQ ID NO 2),

TCT AGC CAT GGC GTT AGT RYG AGT GT (SEQ ID NO 3),

CAC TCG CAA GCA CCC TAT CAG GCA GT (SEQ ID NO 4),

TTG GGC GYG CCC CCG C (SEQ ID NO 20), and

TCT GCG GAA CCG GTG A (SEQ ID NO 27),

or the complement thereof, wherein W represents A or T, R represents G or A, and Y represents T or C.

25. (new) A composition comprising at least one oligonucleotide primer preferably having at least 15 contiguous nucleotides, with said contiguous nucleotides being chosen from any of the following sequences: SEQ ID NOs 1 to 4.

26. (new) A polynucleic acid consisting of 10 to 50 nucleotides which specifically hybridizes with the sequence of SEQ ID NO 20 or the complement thereof under conditions allowing discrimination of up to 1 nucleotide mismatch.

27. (new) A polynucleic acid consisting of 10 to 25 nucleotides which specifically hybridizes with the sequence of SEQ ID NO 27, or the complement thereof.

28. (new) A method for detecting the presence of an infection with an HCV virus in a biological sample by means of a hybridization reaction wherein a polynucleotide of claims 26 or 27 is used as a probe.

29. (new) A method according to claim 28 wherein a polynucleotide with the sequence of SEQ ID NO 20 or 27 or the complement thereof is used as an HCV specific probe.

30. (new) A method according to claim 28 wherein said hybridization reaction is carried out with said probes which are coupled to a solid support, preferably a membrane, and wherein said probes are optionally capture probes.

31. (new) A method according to claim 29 wherein said hybridization reaction is carried out with said probes which are coupled to a solid support, preferably a membrane, and wherein said probes are optionally capture probes.

32. (new) A method for detecting the presence of an infection with an HCV virus in a biological sample by means of an amplification reaction using (a set of) primers that specifically hybridize to SEQ ID NO 1 or SEQ ID NO 2, or the complement thereof; and to SEQ ID NO 3 or SEQ ID NO 4, or the complement thereof.

33. (new) The method according to claim 32 wherein said amplification method is PCR, LCR, NASBA, TAS or amplification by means of Qb replicase.

34. (new) A diagnostic kit for the detection of HCV in a biological sample comprising at least one of the polynucleic acids of any of claims 24 to 26.

35. (new) Probe containing up to 50 nucleotides having at least one of the following universal HCV sequences from the 5'UR region of HCV: SEQ ID NO 20 and 27,

wherein Y represents T or C, or the corresponding sequence wherein T has been replaced by u, or the sequences which are complementary to the above-defined sequences and with said probe being used for the identification of a previously amplified HCV 5'untranslated region fragment.

36. (new) Process for general amplification of the 5' UR region of HCV isolates involving at least one of the following degenerate primers

-a degenerate primer with SEQ ID NO 1, preferably in combination with a primer selected from the region extending from nucleotide -52 to nucleotide -1, such as SEQ ID NO 2, wherein W represents A or T, or the complement of SEQ ID NO 1 or 2,

-a degenerate primer with SEQ ID NO 3, preferably in combination with a primer selected from the region extending from nucleotide -68 to nucleotide -1, such as SEQ ID NO 4, wherein R represents A or G and Y represents T or C, or the complement of SEQ ID NO 3 or 4.--

REMARKS

Claims 1-23 have been canceled, without prejudice.

Claims 24-36 have been added and are pending

The specification has been amended to include the attached Sequence Listing which is a copy of the Sequence Listing filed in paper and computer-readable form in the parent Application No. 09/378,900, with a Statement dated August 23, 1999. No new matter has been added. The Office is requested to use the computer-readable copy of the Sequence Listing from the parent Application No. 09/378,900, for the above-identified application. A separate Request is attached in this regard.

A substitute Power of Attorney and Change of Address Notice is attached and the Office is requested to direct all further communication relating to the above to the undersigned.

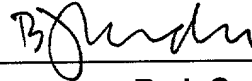
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An early and favorable Action on the merits is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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